



**[BILLING CODE: 6750-01S]**

**FEDERAL TRADE COMMISSION**

**[File No. 121 0144]**

**Novartis AG; Analysis of Agreement Containing Consent Orders to Aid Public Comment**

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

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**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order -- embodied in the consent agreement -- that would settle these allegations.

**DATES:** Comments must be received on or before August 16, 2012.

**ADDRESSES:** Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Novartis Fougara, File No. 121 0144" on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/novartisfougara>, by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Christine Tasso (202-326-2232), FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade

Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 16, 2012), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>. A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 16, 2012. Write "Novartis Fougera, File No. 121 0144" on your comment. Your comment – including your name and your state – will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health

information. In addition, do not include any “[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential,” as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).<sup>1</sup> Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/novartisfougera> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

If you file your comment on paper, write “Novartis Fougera, File No. 121 0144” on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580. If possible, submit your paper comment to the Commission by courier

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<sup>1</sup> In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

or overnight service.

Visit the Commission Website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 16, 2012. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

### **Analysis of Agreement Containing Consent Order to Aid Public Comment**

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Novartis AG ("Novartis") that is designed to remedy the anticompetitive effects of Novartis's acquisition of Fougera Holdings Inc. ("Fougera") in several generic pharmaceutical markets. Under the terms of the proposed Consent Agreement, Novartis is required to: (1) terminate Novartis's marketing agreement with Tolmar, Inc. ("Tolmar") with respect to the currently marketed products generic calcipotriene topical solution, generic lidocaine-prilocaine cream, and generic metronidazole topical gel ("Marketed Divestiture Products") and return all of Novartis's rights to distribute, market, and sell the Marketed Divestiture Products to Tolmar; and (2) return all rights to develop, distribute, market, and sell the development product generic diclofenac sodium gel to Tolmar.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should

withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to an Agreement and Plan of Merger executed on May 1, 2012, Novartis proposes to acquire Fougera in a transaction valued at approximately \$1.525 billion (the “Proposed Acquisition” or “Acquisition”). The Commission’s Complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for generic calcipotriene topical solution, generic lidocaine-prilocaine cream, generic metronidazole topical gel, and diclofenac sodium gel. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Acquisition.

### **The Products and Structure of the Markets**

The Acquisition would reduce the number of generic suppliers in three current generic drug markets with likely anticompetitive consequences. In human pharmaceutical product markets with generic competition, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the limited number of suppliers within each relevant market has a direct and substantial effect on pricing.

Generic calcipotriene topical solution is used to treat chronic, moderately severe scalp psoriasis. Only three companies offer generic calcipotriene topical solution in the United States: Novartis, Fougera, and G & W Laboratories (“G & W”). Novartis leads the market with a 67 percent share. G & W accounts for 22 percent, while Fougera represents an 11 percent share.

Generic lidocaine-prilocaine cream is used as a local anesthetic to treat intact skin and to relieve pain from injections and surgery. Lidocaine-prilocaine is available in both 30 gram tubes

and packages containing five 5 gram tubes (“5-5 tubes”). The 5-5 tubes are used only in hospitals, while the 30 gram tubes are prescribed directly to patients for home use. Fougera, Hi-Tech Pharmaceutical Co. (“Hi-Tech”), and Novartis are the only U.S. suppliers of 30 gram tubes. The market for the generic 5-5 tubes is even more concentrated as only Fougera and Novartis offer them. The Acquisition would therefore create a monopoly in the generic lidocaine-prilocaine 5-5 tube market.

Generic metronidazole topical gel is used to treat inflamed papules and pustules of rosacea, a condition that causes chronic redness of facial skin. Taro Pharmaceutical Industries (“Taro”) is the market leader with approximately 43 percent market share, Fougera has approximately 36 percent market share, Novartis has approximately 19 percent market share, and G & W has approximately 2 percent market share.

Furthermore, the Acquisition could inhibit significant future competition by reducing the number of potential suppliers in the diclofenac sodium gel market. Solaraze is a branded drug sold by Fougera that is used to treat actinic keratosis. No companies currently market a generic version of the drug, diclofenac sodium gel, in the United States. Novartis is best positioned to be the first generic entrant into this market.

### **Entry**

Entry into the relevant markets for the sale of the products would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of drug development times and U.S. Food and Drug Administration (“FDA”) approval requirements are likely to take at least two years.

### **Effects**

In each of the relevant product markets, the Proposed Acquisition likely would eliminate one of a limited number of suppliers and cause significant competitive harm by facilitating price increases – or eliminating decreases – after the transaction is consummated.

In generic pharmaceuticals markets, pricing is heavily influenced by the number of competitors with sufficient supply that participate in the market. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the price of a generic pharmaceutical product decreases with the entry of the second, third, and even fourth and fifth generic competitor. Further, customers generally believe that having at least four suppliers in a generic pharmaceutical market produces the most competitive prices.

Evidence gathered during our investigation indicates that anticompetitive effects are likely to result from a decrease in the number of independent competitors in the markets at issue. The Proposed Acquisition, by reducing an already limited number of competitors or potential competitors in each of these markets, would cause anticompetitive harm to U.S. consumers by increasing the likelihood of higher post-acquisition prices. In the market for generic calcipotriene topical solution, Novartis and Fougera are two of only three suppliers. In the lidocaine-prilocaine cream 30 gram tube market, Novartis and Fougera are two of only three suppliers of the product, and the Proposed Acquisition would eliminate Fougera as an independent competitor to Novartis leaving only Hi-Tech. In the generic lidocaine-prilocaine cream 5-5 gram tubes market, the Acquisition would result in a merger to monopoly. In the generic metronidazole gel market, Novartis and Fougera are two of four competitors, and combined, Novartis and Fougera represent 55 percent of the market. In all of these markets,

industry participants have indicated that the presence of Fougera as a competitor has allowed them to negotiate lower prices.

Finally, the Acquisition would eliminate significant potential competition between Novartis and Fougera in the market for the sale of diclofenac sodium gel. Novartis, through its agreement with Tolmar, was the first to file for an approval of a generic form of Solaraze with the FDA. Thus, Fougera's brand, Solaraze, is likely to face competition solely from Novartis for a significant period of time when generic competition is introduced into this market. As a result, the Acquisition would increase the likelihood that the launch of a generic diclofenac sodium gel product would be delayed or abandoned altogether and increase the likelihood that the combined entity would delay or eliminate the substantial price competition that would have resulted from the entry of a supplier of a generic diclofenac sodium gel product.

### **The Consent Agreement**

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Novartis is required to return certain rights related to the relevant products to Tolmar no later than ten (10) days after the Acquisition. Specifically, the proposed Consent Agreement requires that Novartis: (1) terminate its marketing agreement with Tolmar, thereby returning all of its rights to distribute, market, and sell the Marketed Divestiture Products back to Tolmar; and (2) return all rights to develop, distribute, market, and sell generic diclofenac sodium gel to Tolmar. Tolmar is the Colorado-based developer and manufacturer of the relevant generic products.

If Novartis does not fully comply with its obligations to return all rights to generic calcipotriene topical solution, generic lidocaine-prilocaine cream, generic metronidazole topical gel, and generic diclofenac sodium gel, the Commission may appoint a trustee to effect the return



of such rights.

The proposed remedy contains several provisions to ensure that the transfer of rights back to Tolmar is successful. The Consent Agreement contains an Order to Maintain Assets that requires Novartis to continue to market the Marketed Divestiture Products in a manner that maintains the full economic viability and marketability of the businesses until Tolmar directs Novartis to cease marketing the Marketed Divestiture Products or Tolmar's new marketing partner commences the distribution, marketing, and sale of the Marketed Divestiture Products.

The Commission appointed William Rahe of Quantic Regulatory Services, LLC to act as an interim monitor to assure that Novartis expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Consent Agreement. In order to ensure that the Commission remains informed about the status of the returned rights and assets, the Consent Agreement requires Novartis to file reports with the interim monitor who will report in writing to the Commission concerning performance by Novartis of its obligation under the Consent Agreement.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Richard C. Donohue  
Acting Secretary.

[FR Doc. 2012-17660 Filed 07/19/2012 at 8:45 am; Publication Date: 07/20/2012]